# Tips for Writing User-friendly GMP Document

*"A User-friendly SOP a day keeps the non-compliances away"*

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# Good Documentation

Good documentation is an essential part of a Quality System and is key to operate in compliance with GMP requirements. A Good Documentation System requires well-written documents.

The documents should ensure that processes are well understood and user friendly for everybody. So, they should be designed, prepared, reviewed and distributed with care.

The results of poorly written documentation are:

- Deviations and non-conformances;
- Increased production time due to rework, error correction, etc.;
- Complaints;
- Product Recalls;
- Product Returns;
- Others.

# Other Examples of Situations Caused by Poorly Written Documents…

A poorly written procedure can cause errors, confusion or even team dissatisfaction (for example: if employees do not understand the task and make mistakes during execution, they feel discouraged)

The employee can incorrectly record the information due to a confusing procedure. This causes deviations and loss of traceability.

# Tips for Writing User-Friendly GMP Documents

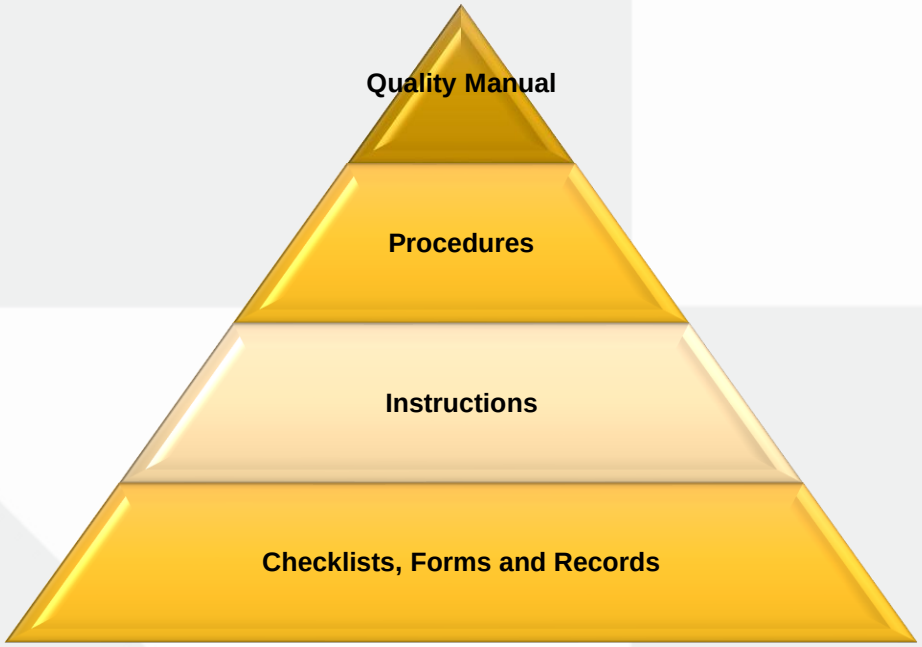
There are some strategies for writing good documents and ensuring that this is not a problem in the company. The following items provide some tips to write user-friendly GMP documentation:

**1 – <u>Determine the document type:</u>**

"All types of document should be defined and adhered to." (*Eudralex – Vol 4 – GMP Guidelines; Chapter 4 - Documentation*)

It is important to determine the document type before starting to write.

Organization of the documentation system promotes maintenance of the information flow and requirements from top down. So, the relationship between all documents (e.g. procedures, instructions, checklists, forms and records) should be clearly indicated within each document so that user can understand how documents are interrelated with each other and where to access the desired information.



# Tips for Writing User-Friendly GMP Documents

**2 – <u>Prepare (and stick to it) Document Templates:</u>**

The use of well-designed templates, per document type, enhances not only the creation but also the understanding of documents. Standardized Templates make documents easy to read and to understand.

**3 – <u>Use a clear title to explain the task</u>:**

Having a title that says exactly what is going to happen in a simple way. The title makes the document easier to understand and to trace later.

**<u>4 – Build the documents in a logical order</u>:**

**“**Documents containing instructions should be laid out in an orderly fashion and be easy to check.” (*Eudralex – Vol 4 – GMP Guidelines; Chapter 4 - Documentation*)

Respect the flow of the process to facilitate understanding, execution and finding of information.

**5 – <u>Describe one task per paragraph</u>:**

Never forget to be simple and objective. Separating by paragraphs can help the reader understand what they need to do. You can enumerate the steps.

# Tips for Writing User-Friendly GMP Documents

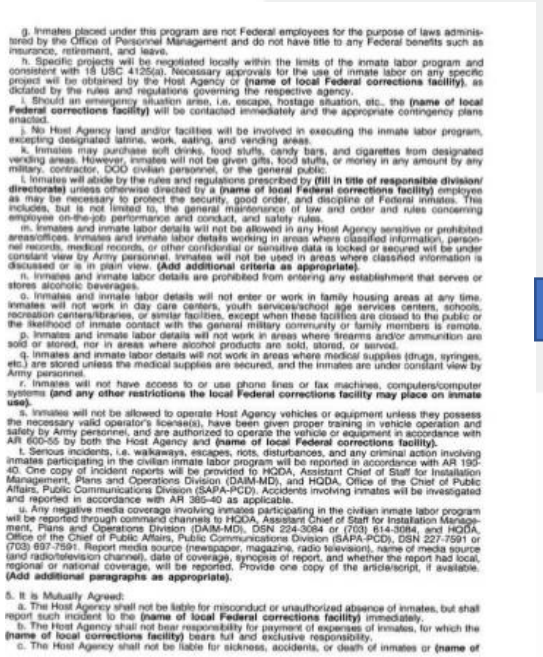
**6 – <u>Pay attention to the language and layout used:</u>**

Write to say what you mean, clearly.

- Keep it simple – don't use unnecessary words
- Write in a language the user, not the writer, will understand
- Use the active voice
- Use specific language
- Avoid dense text – opt for bullet points, lists, tables or images/graphs/flowcharts

"The style and language of documents should fit with their intended use. It's important to use plain language." (*Eudralex – Vol 4 – GMP Guidelines; Chapter 4 - Documentation*)

**Let's move from this:**



g. Inmates placed under this program are not Federal employees for the purpose of laws administered by the Office of Personnel Management and do not have title to any Federal benefits such as insurance, retirement, and leave.

h. Specific projects will be negotiated locally within the limits of the inmate labor program and consistent with 18 USC 4125(a). Necessary approvals for the use of inmate labor on any specific project will be obtained by the Host Agency or **(name of local Federal corrections facility)**, as dictated by the rules and regulations governing the respective agency.

i. Should an emergency situation arise, i.e., escape, hostage situation, etc., the **(name of local Federal corrections facility)** will be contacted immediately and the appropriate contingency plans enacted.

j. No Host Agency land and/or facilities will be involved in executing the inmate labor program, excepting designated latrine, work, eating, and vending areas.

k. Inmates may purchase soft drinks, food stuffs, candy bars, and cigarettes from designated vending areas. However, inmates will not be given gifts, food stuffs, or money in any amount by any military, contractor, DOD civilian personnel, or the general public.

l. Inmates will abide by the rules and regulations prescribed by **(fill in title of responsible division/directorate)** unless otherwise directed by a **(name of local Federal corrections facility)** employee as may be necessary to protect the security, good order, and discipline of Federal inmates. This includes, but is not limited to, the general maintenance of law and order and rules concerning employee on-the-job performance and conduct, and safety rules.

m. Inmates and inmate labor details will not be allowed in any Host Agency sensitive or prohibited areas/offices. Inmates and inmate labor details working in areas where classified information, personnel records, medical records, or other confidential or sensitive data is locked or secured will be under constant view by Army personnel. Inmates will not be used in areas where classified information is discussed or is in plain view. **(Add additional criteria as appropriate).**

n. Inmates and inmate labor details are prohibited from entering any establishment that serves or stores alcoholic beverages.

o. Inmates and inmate labor details will not enter or work in family housing areas at any time. Inmates will not work in day care centers, youth services/school age services centers, schools, recreation centers/libraries, or similar facilities, except when these facilities are closed to the public or the likelihood of inmate contact with the general military community or family members is remote.

p. Inmates and inmate labor details will not work in areas where firearms and/or ammunition are sold or stored, nor in areas where alcohol products are sold, stored, or served.

q. Inmates and inmate labor details will not work in areas where medical supplies (drugs, syringes, etc.) are stored unless the medical supplies are secured, and the inmates are under constant view by Army personnel.

r. Inmates will not have access to or use phone lines or fax machines, computers/computer systems **(and any other restrictions the local Federal corrections facility may place on inmate use).**

s. Inmates will not be allowed to operate Host Agency vehicles or equipment unless they possess the necessary valid operator's license(s), have been given proper training in vehicle operation and safety by Army personnel, and are authorized to operate the vehicle or equipment in accordance with AR 600-55 by both the Host Agency and **(name of local Federal corrections facility).**

t. Serious incidents, i.e. walkaways, escapes, riots, disturbances, and any criminal action involving inmates participating in the civilian inmate labor program will be reported in accordance with AR 190-40. One copy of incident reports will be provided to HQDA, Assistant Chief of Staff for Installation Management, Plans and Operations Division (DAIM-MD), and HQDA, Office of the Chief of Public Affairs, Public Communications Division (SAPA-PCD). Accidents involving inmates will be investigated and reported in accordance with AR 385-40 as applicable.

u. Any negative media coverage involving inmates participating in the civilian inmate labor program will be reported through command channels to HQDA, Assistant Chief of Staff for Installation Management, Plans and Operations Division (DAIM-MD), DSN 224-3084 or (703) 614-3084, and HQDA, Office of the Chief of Public Affairs, Public Communications Division (SAPA-PCD), DSN 227-7591 or (703) 697-7591. Report media source (newspaper, magazine, radio television), name of media source (and radio/television channel), date of coverage, synopsis of report, and whether the report had local, regional or national coverage, will be reported. Provide one copy of the article/script, if available. **(Add additional paragraphs as appropriate).**

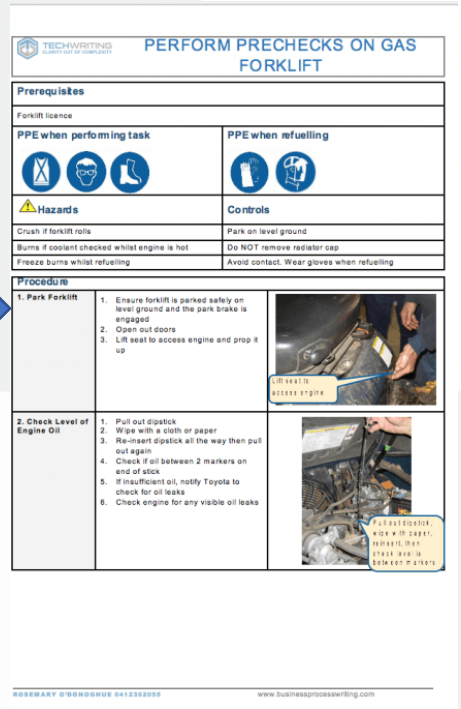
5. It is Mutually Agreed:

a. The Host Agency shall not be liable for misconduct or unauthorized absence of inmates, but shall report such incident to the **(name of local Federal corrections facility)** immediately.

b. The Host Agency shall not bear responsibility for payment of expenses of inmates, for which the **(name of local corrections facility)** bears full and exclusive responsibility.

c. The Host Agency shall not be liable for sickness, accidents, or death of inmates or **(name of**

**To this:**



PERFORM PRECHECKS ON GAS FORKLIFT

| Prerequisites | |
|---|---|
| Forklift licence | |
| PPE when performing task | PPE when refuelling |
| Hazards | Controls |
| Crush if forklift rolls | Park on level ground |
| Burns if coolant checked whilst engine is hot | Do NOT remove radiator cap |
| Freeze burns whilst refuelling | Avoid contact. Wear gloves when refuelling |

**Procedure**

| | | |
|---|---|---|
| 1. Park Forklift | 1. Ensure forklift is parked safely on level ground and the park brake is engaged<br>2. Open out doors<br>3. Lift seat to access engine and prop it up | |
| 2. Check Level of Engine Oil | 1. Pull out dipstick<br>2. Wipe with a cloth or paper<br>3. Re-insert dipstick all the way then pull out again<br>4. Check if oil between 2 markers on end of stick<br>5. If insufficient oil, notify Toyota to check for oil leaks<br>6. Check engine for any visible oil leaks | |

# Tips for Writing User-Friendly GMP Documents

**7 – <u>Use imperative verbs</u>:**

"Standard Operating Procedures, Work Instructions and Methods should be written in an imperative mandatory style." (*Eudralex – Vol 4 – GMP Guidelines; Chapter 4 - Documentation*)

You can use the imperative form to give an order, to give a warming or advice and to make a request. The imperative form provides clear and unambiguous instructions. In this way, the employees understand what they must do and what is required of them. By making instructions mandatory, the chances of deviations and non-conformances are reduced.

**8 – <u>Answer 5 basic questions</u>:**

Make sure your procedure describes "who" does "what", "where", "when" and "how". If the description answers these basic questions, the procedure probably is complete.

# Tips for Writing User-Friendly GMP Documents

**9 – <u>Have a Document Revision History</u>:**

You need to ensure that employees always use the latest version of the document. Documents within the Quality Management System should be regularly reviewed and kept up-to-date. However, it is necessary to ensure that users are always with the latest version.

**10 – <u>Test-drive the documents:</u>**

**“**It is necessary to ensure that what is written is exactly what happens in real practice.” (*Eudralex – Vol 4 – GMP Guidelines; Chapter 4 - Documentation*)

It is common that the writer is not routinely performing the task. It is recommended to test the document with the people who will be using it and incorporate their suggestions.

# Final Remarks

- ✓ Good documentation constitutes an essential part of the Quality System and is key to operating in compliance with GMP requirements and for that, it requires well-written documents.
- ✓ Well-written documents facilitate understanding of employees and reduce chances of deviations, non-conformances and other types of problems in the company.
- ✓ So, a good user friendly documentation facilitates processes understanding for all employees, and should be designed, prepared, reviewed and distributed with care.

# References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3. ICH Q7 – Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients, Step 4 version, https://database.ich.org/sites/default/files/Q7%20Guideline.pdf (Last visited Jun 04,2021).

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- Experience with injectables and solid oral medicines.